

APPENDIX B

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee:	Barry M. Tydings	Examiner:	Jerry D. Johnson
Reexam Control No.:	90/007,813	Group Art Unit:	3991
Patent No.:	6,805,837	Docket No.:	56990-010600
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Customer No.:	33717		
Title:	ASSAYING DEVICE AND METHOD FOR IN FIELD URINALYSIS		

CERTIFICATE UNDER 37 CFR 1.6(d)

I hereby certify that this correspondence and identified enclosures are being transmitted via facsimile only to the Central Reexam Unit at Facsimile No. (571) 273-9900, and Supervisory Patent Examiner Deborah D. Jones at Facsimile No. (571) 273-1535 on August 9, 2007.


Name: Kelly Simpson

DECLARATION OF JAMES G. HIPPLE II IN SUPPORT OF PATENTABILITY OF CLAIMS OVER THE CLAIMS OF PATENT NO. 6,379,620

I, James G. Hipple II, declare as follows:

1. I am the Owner and President of Drug Free Work Place Administration Inc. of 723 So. Casino Blvd., 2nd Floor, Las Vegas, Nevada 89101.
2. My company distributes urine drug testing kits world wide. I have worked in the field of drug testing since 1997, and I know the field well, including different technical aspects relating to different test cup constructions. As part of my business I am aware of many different test kits that are on the market. I am very familiar with advantages and disadvantages of different kits from a technical perspective.
3. I know and understand well the old urine kit from about 1998 that related to an assay where the wicking extended from one side of a backing over the top of a backing and down the other side of the backing, as I tried to market it for many months in 1998. These cups were obtained from Barry Tydings.

4. With the wick system of that test kit my customers experienced problems with wicking, migration and flooding of urine on the wick and the assay strip. Often when there was too much urine in the cup, the urine would flood the assay strip, and render the test invalid. When there was too little urine in the cup, the urine would not reach the assay test strip, and the test would be useless. These test cups were so inconsistent in a technical performance sense, that I had great difficulty in establishing any viable business for such testing techniques, as I had so many returns relating to the cup not working properly.

5. When a new solution was presented to me which avoided these problems of the wicking over the top of the backing, namely an assay system where the urine flow did not flow with the wicking extending over the top, this was a dramatic change in the technology, the business and the ability to establish a viable market for urine test cups.

6. I am a person of ordinary skill in the art of urine drug testing cups. Even though I have been involved in many aspects of these kinds of test cups since 1997, it would not have, and did not occur to me that having the urine wick solely up the wicking, or up the assay strip would solve all the prior problems with cups. The up the wick/up the strip construction is an important advance scientifically and technically to the over the over the top wicking of the prior technology. Such cups are far superior to the prior problematic over the top wicking construction.

7. Changing the construction from over-the-top wick construction to the construction of wicking up the wick and up the strip was not an obvious change, and it was an important advance which took ingenuity. It would not have been obvious to anyone of skill in the art at the time and who was actually struggling with the real problems of making a workable reliable product, that this totally different construction would actually work and solve those previously unsolved problems.

8. I worked with Barry Tydings in 1998 and 1999 explaining the problems that his cups were presenting to my customers. For several months, we brainstormed about solutions to the problem: These included using different qualities and quantities of adhesive tape to change the bonding and securing characteristics of the assay strip and wicking material to each other and to the underlying substrate holding them in the assay cup. We also considered the possibility of

different thicknesses of wicking material to facilitate the better and more consistent urine flow and the overall cup construction modifications. The assembly of the different components was largely manual, and that was problematic. We investigated the possibility of automating the manufacturing, but this proved to be prohibitively expensive. No ready solution appeared to us.

10. The only competitor cup we could look at for ideas was the Roche cup, (Galloway Patent No.5,403,551) but this worked on a different principle, namely the down the strip urine flow. There was nothing that led us to the solution that Barry Tydings ultimately came up with, namely the up the wick/up the strip construction.

11. The up the wick/up the strip construction solved the problems being experienced with the wicking over the top construction. The up the strip wicking functions differently from a down the wick flow of urine, which was a characteristic of the over the top wicking construction. It would not have been obvious to make the change of flow and appreciate that it would function and be operable.

12. I now compete in business with many other cups having the structure and functional flow characteristics of the up the wick/up the strip construction. These are copies of the up the wick/up the strip system that overcame the prior unworkable structure, and they did not exist before the Barry Tydings solution.

All statements made herein of my own knowledge are true, all statements made hereon information and belief are believed to be true, and further these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under U.S.C. 1001, and may jeopardize the validity of the application of any patent issuing thereon.

Dated: 8-9-07
JAMES G. HIPPLE II